



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

Re: Posicor®  
Docket No. 97E-0462

The Honorable Q. Todd Dickinson  
Deputy Assistant Commissioner for  
Patent Policy and Projects  
Office of the Assistant Commissioner for Patents  
U.S. Patent and Trademark Office  
Crystal Park Building 2, Suite 919  
Washington, DC 20231

APR 13 1999

Dear Commissioner Dickinson:

This is in regard to the patent term extension application for U.S. Patent No. 4,808,605 filed by Hoffman-La Roche, Inc. under 35 U.S.C. § 156. The patent claims the human drug product Posicor® (mibefradil dihydrochloride), new drug application NDA 20-689.

In the August 4, 1998, issue of the Federal Register (63 Fed. Reg. 41582), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before February 1, 1999, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs

cc: George W. Johnstone  
Hoffman-La Roche, Inc.  
Patent Law Department  
340 Kingsland Street  
Nutley, NJ 07110

97E-0462

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**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service  
Food and Drug Administration

APR 13 1999  
Memorandum

Date: APR 13 1999

From: Brian J. Malkin, Associate Director for Patents and Hearings  
Health Assessment Policy Staff (HFY-20)

Subject: Patent Term Restoration Application  
for Posicor<sup>®</sup>

To: Dockets Management (HFA-305)

Attached is a letter to the Patent Term Office for the above mentioned drug under the Docket Number **97E-0462** stating that this particular patent is eligible for regulatory review. The Patent Number is **4,808,605**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.